

EXHIBIT 7

Protected Information - Benjamin Lebwohl, M.D., M.S.

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3
4 - - -
5

6 IN RE: BENICAR : Civil No.
7 (OLMESARTAN) PRODUCT : 15-2606 (RBK) (JS)
8 LIABILITY LITIGATION :
9 :
10 - - -

11 February 10, 2017
12 - - -

13 PROTECTED INFORMATION
14 - - -

15 Oral expert deposition of
16 BENJAMIN LEBWOHL, M.D., M.S., taken
17 pursuant to notice, was held at the law
18 offices of Robins Kaplan LLP, 601
19 Lexington Avenue, Suite 3400, New York,
20 New York, beginning at 9:45 a.m., on the
21 above date, before Kimberly A. Cahill, a
22 Federally Approved Registered Merit
23 Reporter and Notary Public.
24

21 - - -
22 GOLKOW TECHNOLOGIES, INC.
23 877.370.3377 ph | 917.591.5672 fax
24 deps@golkow.com

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 2

1 APPEARANCES:
2 MAZIE SLATER KATZ & FREEMAN, LLC
3 BY: ADAM M. SLATER, ESQUIRE
4 103 Eisenhower Parkway, 2nd Floor
5 Roseland, New Jersey 07068
6 (973) 228-9898
7 aslater@mskf.net
8 Representing the Plaintiffs
9 ROBINS KAPLAN LLP
10 BY: RAYNA E. KESSLER, ESQUIRE
11 601 Lexington Avenue
12 Suite 3400
13 New York, New York 10022
14 (212) 980-7400
15 rkessler@robinskaplan.com
16 Representing the Plaintiffs
17 DRINKER BIDDLE & REATH LLP
18 BY: KENNETH A. MURPHY, ESQUIRE
19 One Logan Square, Suite 2000
20 18th and Cherry Streets
21 Philadelphia, Pennsylvania 19103
22 (215) 988-2700
23 kenneth.murphy@dbr.com
24 Representing Daiichi Sankyo, Inc.
DRINKER BIDDLE & REATH LLP
BY: JESSICA L. BRENNAN, ESQUIRE
600 Campus Drive
Florham Park, New Jersey 07932
(973) 549-7000
jessica.brennan@dbr.com
Representing Daiichi Sankyo, Inc.

Page 4

1 INDEX
2
3
4
5 Testimony of: BENJAMIN LEBWOHL, M.D.,
6 M.S.
7 By Mr. Murphy 9
8 By Mr. Slater 367
9
10 EXHIBITS
11
12
13
14
15
16
17
18
19
20
21
22
23
24

NO.	DESCRIPTION	PAGE
Lebwohl-1	Notice of Deposition of Benjamin Lebwohl, M.D.	9
Lebwohl-2	Plaintiffs' Responses and Objections to Defendants' Requests in Schedule A of Benjamin Lebwohl, M.D.'s Notice of Deposition	14
Lebwohl-3	5/5/15 Invoice from Lebwohl to Slater	28
Lebwohl-4	Rule 26 Expert Report of Benjamin Lebwohl Regarding General Causation	34
Lebwohl-5	2/9/17 Letter from Slater to Sharko	35
Lebwohl-6	9/23/16, 11/18/16, 38 and 11/29/16 Invoices from Lebwohl to Slater	88
Lebwohl-7	Document Entitled "In re: Benicar (Olmesartan) Products Liability Litigation Supplemental Reliance List for Dr. Benjamin Lebwohl"	178
Lebwohl-8	2014 Paper "Sprue-like Enteropathy Associated with Olmesartan" by Cartee and Murray	200
Lebwohl-9	2013 Paper "Villous Atrophy and Negative Celiac Serology: A Diagnostic and Therapeutic Dilemma" by DeGaetano, et al	255
Lebwohl-10	2015 Paper "Immunopathogenesis of olmesartan-associated enteropathy" by Marietta, et al	262
Lebwohl-11	2014 Paper "Olmesartan, Other Antihypertensives, and Chronic Diarrhea Among	

Page 3

1 ALSO PRESENT:
2 Amy Klug, Esquire
3 Assistant General Counsel
4 Daiichi Sankyo, Inc.
5
6
7 - - -
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

Page 5

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 6	Page 8
<p>1 Patients Undergoing 2 Endoscopic 3 Procedures: A 4 Case-Control Study" 271 5 by Greywoode 6 Article "Sprue-like 7 histology in 8 patients with 9 abdominal pain 10 taking olmesartan 11 compared with other 12 angiotensin 13 receptor blockers" 14 by Lagana, et al 15 16 Lebwohl-13 10/10/15 MedWatch 307 17 Report (Also Marked 18 as Exhibit 749) 19 OLM-DSI-0004775145- 20 R and 21 OLM-DSI-0004775146- 22 R 23 24 Lebwohl-14 10/11/15 MedWatch 320 25 Report (Also Marked 26 as Exhibit 347) 27 OLM-DSI-0004774183- 28 R and 29 OLM-DSI-0004774184- 30 R 31 32 Lebwohl-15 Excerpts from the 335 33 May 31, 2016 34 Deposition 35 Transcript of 36 Yasushi Hasebe 37 38 Lebwohl-16 Sankyo Post 339 39 Marketing Safety 40 Adverse Event 41 Contact Log 42 Attaching 7/19/05 43 Med Watch Report 44 (Also Marked as Exhibit 129),</p>	<p>1 - - - 2 DEPOSITION SUPPORT INDEX 3 - - - 4 5 Direction to Witness Not to Answer 6 Page Line Page Line Page Line 7 46 19 8 9 Request for Production of Documents 10 Page Line Page Line Page Line 11 198 10 12 13 Stipulations 14 Page Line Page Line Page Line 15 16 Question Marked 17 18 Page Line Page Line Page Line 19 20 21 22 23 24</p>
Page 7	Page 9
<p>1 OLM-DSI-0011876006 2 through 3 OLM-DSI-0011876014 4 Lebwohl-17 9/21/05 E-Mail from 346 5 Robinson to Risk 6 Management 7 Attaching Two 8 CIOMS, etc. (Also 9 Marked as Exhibit 10 130), 11 OLM-DSI-0011876015 12 through 13 OLM-DSI-0011876036 14 15 Lebwohl-18 List of Search 358 16 Terms 17 18 19 20 21 22 23 24</p>	<p>1 - - - 2 (Deposition Exhibit No. 3 Lebwohl-1, Notice of Deposition of 4 Benjamin Lebwohl, M.D., was marked 5 for identification.) 6 - - - 7 BENJAMIN LEBWOHL, M.D., 8 M.S., after having affirmed, was 9 examined and testified as follows: 10 - - - 11 EXAMINATION 12 - - - 13 BY MR. MURPHY: 14 Q. Good morning, Dr. Lebwohl. 15 A. Good morning. 16 Q. My name is Ken Murphy. I am 17 the attorney representing the Daiichi 18 defendants in the litigation that brings 19 us here today, and this is an opportunity 20 for me to ask you some questions. 21 I'll start with a couple of 22 preliminary instructions. The first is, 23 if there is anything about a question 24 that I pose to you that you don't</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 10	Page 12
<p>1 understand or if you have any question in 2 your mind about what I mean, so indicate. 3 I'll try to rephrase or explain myself. 4 Fair enough? 5 A. Yes. 6 Q. Okay. 7 The assumption by all will 8 be that if you answer the question that I 9 asked, that you indeed understood what I 10 was asking you. 11 I would ask that you keep 12 your responses verbal. Nods of the head, 13 shrugs of the shoulders, uh-huh, uh-uh, 14 kind of difficult for Ms. Cahill to 15 properly record. So I will ask that you 16 keep your responses verbal to yes, no, or 17 whatever explanation you require. 18 Okay? 19 A. I understand. 20 Q. Okay. And your last name, I 21 want to make sure I am pronouncing it 22 correctly, is it Lebwohl? 23 A. You got it. 24 Q. Okay.</p>	<p>1 items? 2 A. I have a binder on my person 3 that I've brought. 4 Q. Okay. And what -- the 5 materials that are in the binder, what 6 are they? 7 A. They are documents relating 8 to the literature review. I believe the 9 legal term is my reliance list. 10 Q. Okay. 11 A. I've also -- in addition to 12 published papers in the binder, I also 13 have my own report, a paper copy of my 14 own report, and expert reports by Drs. 15 Wilson and Turner, as well as an FDA drug 16 safety communication. 17 MR. SLATER: And, counsel, 18 obviously I handed you the 19 invoices at the start before we 20 went on the record, so you have 21 all the invoices. 22 MR. MURPHY: Correct. 23 MR. SLATER: Other than the 24 one that I withhold as work</p>
Page 11	Page 13
<p>1 I want to show you or 2 provide you what's been marked as Exhibit 3 No. 1 for the deposition. That's the 4 Notice of Deposition that was issued to 5 counsel. 6 My question to you is 7 whether you've seen that, that is, 8 Exhibit No. 1, before. 9 A. I have. 10 Q. Accompanying the notice is a 11 Schedule A that asks you to bring with 12 you certain documents. Do you see that? 13 A. Is this in the same packet 14 that you just provided? 15 Q. Do you see Schedule A? 16 A. I see Schedule A at the top. 17 Q. Yes. 18 A. And so, yes, I see it. 19 Q. Okay. And Schedule A asks 20 you to bring with you certain documents 21 and other items. Do you see that? 22 A. I see that. 23 Q. Okay. 24 Did you bring any of those</p>	<p>1 product because that case is not a 2 case where Dr. Lebwohl's been 3 disclosed as an expert. 4 MR. MURPHY: Understood. 5 BY MR. MURPHY: 6 Q. Is there anything requested 7 in Schedule A -- any request, document 8 request, in Schedule A -- that you have 9 not satisfied? 10 MR. SLATER: Counsel, you 11 realize that we provided to you 12 our responses which have our 13 formal responses and objections. 14 Right? And you realize that's 15 something that an attorney would 16 have input into as well. Right? 17 MR. MURPHY: I'm going to 18 get there in a moment, but to 19 answer your question, yes, I 20 acknowledge that you provided 21 objections and responses 22 yesterday. I'm simply curious to 23 know what the doctor's response is 24 to my question.</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 14	Page 16
<p>1 THE WITNESS: In</p> <p>2 consultation with counsel, I</p> <p>3 believe that I've satisfied these</p> <p>4 requests.</p> <p>5 MR. MURPHY: Okay.</p> <p>6 Let's mark this as 2.</p> <p>7 - - -</p> <p>8 (Deposition Exhibit No.</p> <p>9 Lebwohl-2, Plaintiffs' Responses</p> <p>10 and Objections to Defendants'</p> <p>11 Requests in Schedule A of Benjamin</p> <p>12 Lebwohl, M.D.'s Notice of</p> <p>13 Deposition, was marked for</p> <p>14 identification.)</p> <p>15 - - -</p> <p>16 BY MR. MURPHY:</p> <p>17 Q. Doctor, we've marked as</p> <p>18 Exhibit 2 to your deposition a document</p> <p>19 that we received from your counsel titled</p> <p>20 "Plaintiffs' Responses and Objections to"</p> <p>21 --</p> <p>22 MR. SLATER: I'm not his</p> <p>23 counsel, but we know what you</p> <p>24 mean.</p>	<p>1 When you generated this binder or you</p> <p>2 prepared this binder, what was the</p> <p>3 purpose for preparing the binder?</p> <p>4 MR. SLATER: Objection to</p> <p>5 form.</p> <p>6 You can answer the question.</p> <p>7 THE WITNESS: Mr. Slater</p> <p>8 advised that it would be</p> <p>9 beneficial to have easy access to</p> <p>10 relevant literature on the topic</p> <p>11 for the day.</p> <p>12 BY MR. MURPHY:</p> <p>13 Q. And the relevant -- and</p> <p>14 strike that.</p> <p>15 The documents that you refer</p> <p>16 to as the relevant literature, does the</p> <p>17 relevant literature include all of the</p> <p>18 literature upon which you rely for your</p> <p>19 opinion?</p> <p>20 A. In terms of immediate or</p> <p>21 relevant literature, yes, but I'm also</p> <p>22 relying on my experience with patients as</p> <p>23 well as my experience in medicine,</p> <p>24 clinical medicine, evidence-based</p>
Page 15	Page 17
<p>1 MR. MURPHY: Okay.</p> <p>2 BY MR. MURPHY:</p> <p>3 Q. -- "to Defendants' Requests</p> <p>4 in Schedule A of Benjamin Lebwohl, M.D.'s</p> <p>5 Notice of Deposition."</p> <p>6 My question to you is, have</p> <p>7 you seen this document before?</p> <p>8 A. Yes.</p> <p>9 Q. And when did you see it?</p> <p>10 A. I saw this document</p> <p>11 yesterday.</p> <p>12 Q. The binder that you brought</p> <p>13 with you today, among other things, it</p> <p>14 includes the items that you reference in</p> <p>15 your -- in the reliance list that is</p> <p>16 attached to your report; correct?</p> <p>17 A. Correct.</p> <p>18 Q. Does it also include items</p> <p>19 that were identified in a supplemental</p> <p>20 reliance list that you provided?</p> <p>21 A. Can I see our supplemental</p> <p>22 reliance list? I just want to make sure</p> <p>23 that -- that I'm answering accurately.</p> <p>24 Q. Well, let me ask you this:</p>	<p>1 medicine, and epidemiology.</p> <p>2 And so, for example, if I</p> <p>3 took course work in epidemiology and I'm</p> <p>4 relying on my -- what I've learned from</p> <p>5 that course work, of course that's not</p> <p>6 going to be in this binder.</p> <p>7 Q. Just so that I am clear, my</p> <p>8 question was focused on the literature,</p> <p>9 and so I'm simply trying to determine</p> <p>10 whether all of the literature that you</p> <p>11 have in that binder constitutes the</p> <p>12 literature upon which you rely for your</p> <p>13 opinion.</p> <p>14 A. The olmesartan</p> <p>15 specific-related literature, I'd say yes.</p> <p>16 Q. Does the binder include</p> <p>17 literature that is not</p> <p>18 olmesartan-specific?</p> <p>19 A. Yes, and I can give you an</p> <p>20 example if you'd like.</p> <p>21 Q. You can give me an example?</p> <p>22 A. Yes.</p> <p>23 Q. Please do.</p> <p>24 A. So, for example -- and this</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 18	Page 20
<p>1 is on my reliance list -- Lebwohl, et al, 2 "Sex and racial disparities in duodenal 3 biopsy to evaluate for celiac disease" 4 which we published in Gastrointestinal 5 Endoscopy gastroenterology journal in 6 2012. 7 Q. That is an example of a 8 piece of literature upon which you do not 9 rely to support your opinion. 10 MR. SLATER: Objection; 11 mischaracterization, foundation. 12 MR. MURPHY: That's a 13 question. I didn't make a 14 statement. I asked a question. 15 MR. SLATER: Well, you kind 16 of did, actually, so I'm going to 17 object the way I think I need to. 18 MR. MURPHY: That's fair, 19 Mr. Slater. 20 MR. SLATER: I know it's 21 fair, thank you. 22 MR. MURPHY: I'll rephrase 23 the question. 24 MR. SLATER: You don't have</p>	<p>1 and we may get there. 2 MR. SLATER: Let him 3 struggle through it and then you 4 can answer it. 5 BY MR. MURPHY: 6 Q. Literature that is not 7 directly related to olmesartan, is there 8 literature not directly to olmesartan 9 that you rely upon to support your 10 opinion? 11 A. There is certainly 12 literature that doesn't mention 13 olmesartan by name, for example, 14 literature on celiac disease for which 15 there are certain analogies to olmesartan 16 enteropathy, but -- that are in this 17 binder that I do indeed rely upon. 18 However, if you were to look 19 at the full text of this article, you 20 wouldn't find the word "olmesartan"; and 21 if you were to ask clinicians or experts 22 in olmesartan enteropathy, they might not 23 come to mind to reference this paper. 24 As I was the first author of</p>
Page 19	Page 21
<p>1 to. You don't have to trust me. 2 MR. MURPHY: I'll rephrase 3 the question. 4 BY MR. MURPHY: 5 Q. The article that you just 6 identified, is that an example of an 7 article upon which you do not rely to 8 support your opinion as set forth in your 9 report? 10 MR. SLATER: Objection; 11 mischaracterization, foundation -- 12 THE WITNESS: That is not 13 such an example. I believe the 14 question -- perhaps it could be 15 read back -- was whether there was 16 literature in this binder that was 17 not directly related to 18 olmesartan. 19 BY MR. MURPHY: 20 Q. Right. And so the question 21 then becomes, literature that is not 22 directly related to olmesartan -- 23 A. Or perhaps I can clarify. 24 Q. Let me ask you a question</p>	<p>1 this paper, I'm intimately aware of what 2 we did in that paper. I thought that it 3 was relevant to cite it because I learned 4 a fair amount about misdiagnosis or 5 underdiagnosis when I was researching 6 that specific study. 7 But I believe the question 8 was whether there were any articles that 9 are olmesartan-related articles and I 10 think that I rely on this even though one 11 wouldn't immediately assume that this is 12 an olmesartan-related article. 13 Q. I appreciate your response. 14 Are there any articles in that binder 15 that you don't rely upon in setting forth 16 your opinion? 17 (Pause.) 18 THE WITNESS: These are all 19 appropriate to be on a reliance 20 list. 21 BY MR. MURPHY: 22 Q. My question is, are there 23 any there that you don't rely upon? I 24 understand that you're saying they're all</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 22	Page 24
<p>1 appropriate to be on the reliance list, 2 but do you rely upon all of them? 3 A. None of them are a linchpin, 4 if that's what you mean, but I have made 5 reference to them or I find that they are 6 relevant to the discussion, if that's 7 what you mean by relying upon. There are 8 none that should be taken off. 9 If there were serious 10 problems, for example, with any one of 11 these, I don't think it would be accurate 12 to say that, well, I rely on all of 13 these; and so if this one has serious 14 problems, then there's a problem with my 15 overall conclusion. 16 But I think that they are 17 all relevant in one way or another. 18 Q. Okay. 19 Dr. Lebwohl, how many times 20 have you testified as an expert witness 21 at trial? 22 A. I've never testified as an 23 expert witness at trial. 24 Q. How many times have you</p>	<p>1 MR. SLATER: With the 2 exception of what we're doing with 3 Benicar, counsel? 4 I'm asking you to clarify. 5 Are you including this litigation 6 or -- 7 MR. MURPHY: Other than what 8 brings us here today. 9 MR. SLATER: Okay. Thank 10 you for your clarification. It 11 was much appreciated. 12 THE WITNESS: No, I have 13 not. 14 BY MR. MURPHY: 15 Q. The medical malpractice 16 matter that you referenced earlier, did 17 you generate a report in that matter? 18 A. I did not generate a written 19 report to the best of my recollection, 20 but it was a few years ago. I think I 21 would have remembered writing it, but I'm 22 fairly confident that it was all -- that 23 my services involved reviewing files, 24 conversation with the attorney, followed</p>
Page 23	Page 25
<p>1 offered deposition testimony as an 2 expert? 3 A. I've offered deposition -- 4 or I've been deposed as an expert once. 5 Q. And when was that? 6 A. It was in December 2012. 7 Q. What type of matter was 8 that? 9 A. It was a medical malpractice 10 case. 11 Q. And by whom were you -- or 12 on whose behalf were you engaged, the 13 plaintiff or the defendant? 14 A. I was engaged by the 15 defendant. 16 Q. Have you ever had occasion 17 to offer any testimony regarding 18 causation where a drug was alleged to 19 cause injury to someone? 20 A. Can you repeat the question? 21 Q. Sure. Have you ever had 22 occasion to offer expert testimony in a 23 litigation where the allegation is that a 24 drug caused injury to someone?</p>	<p>1 by -- followed by a deposition. 2 I'm just not sure if there 3 were any, for example, brief attestations 4 confirming my opinion that I needed to 5 sign, but I certainly didn't prepare the 6 kind of report that I went into when 7 preparing this current report under 8 question. 9 Q. So you don't recall 10 generating a report, but if you did 11 generate a report, it wasn't like the one 12 you've generated in this litigation; is 13 that your -- what you're telling me? 14 A. Yes. 15 Q. What was the alleged 16 malpractice in the matter where you 17 provided expert testimony? 18 A. It was a medical malpractice 19 case and I'm honestly not sure how many 20 of the details I am supposed to be 21 granting or divulging to people who were 22 not involved in the case. 23 If Mr. Slater believes that 24 I am obligated to describe everything I</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 26	Page 28
<p>1 remember from the case and he thinks that 2 that is a legitimate thing to do that 3 wouldn't violate any legal or medical or 4 ethical norms, I would go ahead and do 5 so, but I'd like to check with him first. 6 I hope you understand. 7 MR. SLATER: Yeah, if you 8 were deposed and they took your 9 deposition, I mean, as long as -- 10 he's not going to ask you what you 11 discussed with the attorneys 12 because obviously that, I wouldn't 13 think that you would answer. 14 He just I think wants to 15 know generally what was the 16 medical issue. 17 MR. MURPHY: That is 18 correct. 19 THE WITNESS: In that case, 20 the medical issue was a case of 21 colon cancer and the issue at play 22 was whether the colonoscopies 23 performed prior to the colon 24 cancer diagnosis met the standard</p>	<p>1 pin a date on it, I think it wouldn't be 2 until sometime in 2016 when I realized 3 that the question at hand that I was 4 going to be addressing was regarding 5 general causation. 6 MR. MURPHY: Let's mark this 7 as Exhibit 3. 8 - - - 9 (Deposition Exhibit No. 10 Lebwohl-3, 5/5/15 Invoice from 11 Lebwohl to Slater, was marked for 12 identification.) 13 - - - 14 BY MR. MURPHY: 15 Q. Dr. Lebwohl, I've handed you 16 what's been marked as Exhibit 3 to your 17 deposition. It is one of a number of 18 invoices that Mr. Slater provided to me 19 earlier today. 20 This particular invoice has 21 a date of May 5th, 2015. Do you see 22 that? 23 A. I do. 24 Q. And this is -- was this an</p>
Page 27	Page 29
<p>1 of care. 2 MR. MURPHY: Okay. Thank 3 you. 4 BY MR. MURPHY: 5 Q. With regard to this 6 litigation that brings us here today 7 involving olmesartan, when were you 8 initially engaged as an expert witness? 9 A. I'm not sure precisely when 10 I formally agreed to be an expert 11 witness, but I can tell you, if this is 12 what you're looking for, when I first 13 communicated with Adam Slater. 14 Q. My question to you is 15 slightly different. When were you first 16 approached regarding the prospect of you 17 serving as an expert witness in this 18 litigation? 19 A. I'm not sure when precisely 20 I said yes to be an expert witness, 21 because this was a conversation that 22 evolved over the course of a number of 23 months. 24 I -- probably if I had to</p>	<p>1 invoice that you submitted to Mr. Slater? 2 A. It was. 3 Q. And below -- or I should 4 say, on the document, among other things, 5 you have dates and you have description 6 of a task that you performed; correct? 7 A. Correct. 8 Q. And the first date we see 9 there is 4/14/2015; correct? 10 A. Correct. 11 Q. So you would agree with me 12 that you were approached about the 13 prospect of being an expert in this 14 litigation at some point prior to April 15 of 2015; correct? 16 MR. SLATER: Objection. 17 You can answer. 18 THE WITNESS: I was 19 certainly approached for my advice 20 and expertise by Mr. Slater before 21 April 2015. 22 BY MR. MURPHY: 23 Q. Okay. 24 So when were you first</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 30	Page 32
<p>1 approached by Mr. Slater for your advice 2 and expertise regarding this litigation, 3 specifically olmesartan? 4 A. To the best of my 5 recollection, I believe it was early 6 2015, give or take a couple of months. 7 Q. And before Mr. Slater 8 contacted you in early 2015 about this 9 litigation, had any other attorney 10 approached you regarding this litigation? 11 A. To the best of my 12 recollection, no. That said, I get a lot 13 of e-mails, but -- and it's possible that 14 I might have either missed or I'm not 15 remembering any specific one, but I 16 certainly didn't respond, if I got any. 17 Q. But when Mr. Slater reached 18 out to you, that's when you began, in 19 your view, to function as an expert in 20 this litigation; is that fair to say? 21 MR. SLATER: Objection. 22 You may answer. 23 THE WITNESS: No. I 24 consider myself an expert in</p>	<p>1 have no quibble with it, and just so that 2 we're on page, so as best you recall, it 3 was in or about early 2015 when you began 4 functioning as an expert in this 5 litigation on behalf of Mr. Slater; is 6 that correct? 7 A. That sounds right. 8 Q. And what were you asked to 9 do? 10 A. By Mr. Slater? 11 Q. Yes. 12 MR. SLATER: And just he's 13 only asking in the very general 14 sense, because our communications, 15 that would be work product he's 16 not going to ask about. 17 MR. MURPHY: And to be 18 clear, to set the tone for the 19 day, I will never ask you about 20 conversations you had with Mr. 21 Slater or any other counsel for 22 plaintiffs. I'm not interested in 23 particulars in that regard. 24 I simply at this point am</p>
Page 31	Page 33
<p>1 olmesartan enteropathy -- 2 MR. MURPHY: In this 3 litigation. I'll rephrase the 4 question. 5 BY MR. MURPHY: 6 Q. When Mr. Slater reached out 7 to you, that is when you became an expert 8 in this litigation; correct? 9 MR. SLATER: Objection. 10 You can answer. 11 THE WITNESS: I would like 12 to think that I was an expert on 13 this subject matter that is being 14 litigated well before he reached 15 out to me. Indeed, I think that's 16 why he reached out to me. 17 But I began my engagement in 18 this particular litigation in my 19 role as an expert at that time. I 20 contend, though, that I was an 21 expert in the subject matter 22 before then. 23 BY MR. MURPHY: 24 Q. And that I understand and I</p>	<p>1 trying to determine what were you 2 asked to do as an expert when you 3 were engaged by Mr. Slater. Your 4 task was what? 5 THE WITNESS: I see. 6 Initially, to the best of my 7 recollection, he asked for advice 8 on this entity of olmesartan 9 enteropathy, specifically what I 10 thought was going on, what my 11 opinion was about olmesartan and 12 enteropathy, my opinion on the 13 literature at the time. We had 14 several conversations related to 15 that. 16 He asked me to summarize 17 what I knew about the existing 18 literature; and at some point, he 19 began bringing up additional parts 20 of the medical literature that I 21 had not yet seen and he asked my 22 opinion on that. 23 And again at some point, he 24 asked me to review some cases of</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

<p style="text-align: right;">Page 34</p> <p>1 potential olmesartan enteropathy 2 and he asked my opinion on those. 3 BY MR. MURPHY: 4 Q. Had you ever worked with Mr. 5 Slater prior to the time he reached out 6 to you in early 2015? 7 A. No. In fact, I'd never met 8 him before that time. 9 MR. MURPHY: This is 4. 10 - - - 11 (Deposition Exhibit No. 12 Lebwohl-4, Rule 26 Expert Report 13 of Benjamin Lebwohl Regarding 14 General Causation, was marked for 15 identification.) 16 - - - 17 BY MR. MURPHY: 18 Q. Doctor, we've handed you 19 what's been marked as Exhibit 4 to your 20 deposition. That appears to be a report 21 that you generated, along with -- and two 22 exhibits. 23 Is that what you recognize 24 it to be?</p>	<p style="text-align: right;">Page 36</p> <p>1 identification.) 2 - - - 3 BY MR. MURPHY: 4 Q. So you now have in front of 5 you what's been marked as Exhibit 5. Is 6 that the addendum to which you refer? 7 A. Yes. Thank you. 8 Q. And so do Exhibits 4 and 5 9 constitute your report in this case? 10 MR. SLATER: Objection. 11 You can answer. 12 THE WITNESS: Yes, Exhibit 4 13 plus Exhibit 5 are my report. 14 BY MR. MURPHY: 15 Q. Focusing on Exhibit 4, which 16 is the report, or at least the first 17 iteration of the report without the 18 addendum and modification, how long did 19 it take you to generate that report? 20 A. I think it would depend a 21 bit on whether you mean the actual 22 writing time, typing time, or if you 23 would also include supplemental 24 literature review, conversations back and</p>
<p style="text-align: right;">Page 35</p> <p>1 A. It is, though I'm not sure 2 what you mean by the two exhibits. Do 3 you mean the Exhibit 1 and Exhibit 2 at 4 the back of this packet? That's what you 5 mean? 6 Q. Yes, Doctor. 7 A. Not -- okay. Because this 8 is called Exhibit 4, so I just wanted to 9 make sure. 10 Also, I believe there is 11 either -- it's an addendum or 12 modification to the report that we also 13 either submitted or I signed -- that I 14 signed, so I would say this is not the 15 complete report in that manner of 16 speaking. 17 MR. SLATER: I think he 18 might be talking about the letter 19 I sent you yesterday. 20 MR. MURPHY: Sure. 21 - - - 22 (Deposition Exhibit No. 23 Lebwohl-5, 2/9/17 Letter from 24 Slater to Sharko, was marked for</p>	<p style="text-align: right;">Page 37</p> <p>1 forth with Mr. Slater. So I would ask 2 you to clarify? 3 Q. Sure. 4 I'll approach it slightly 5 differently: When did you begin writing 6 the report? 7 A. I began the daunting task of 8 facing a blank page on the computer, I 9 believe, in late October. 10 Q. Late October of 2016? 11 A. Yes. 12 Q. And when did you complete 13 that task? 14 A. I believe I signed the final 15 version of the report on the day it was 16 due, on or abouts, maybe the day before. 17 Q. Now, if you look to page 44 18 of the exhibit, there is a date of 19 November 30. As best you recall, was 20 that the date that you completed it? 21 A. As best I recall, yes. 22 MR. MURPHY: Let's mark this 23 as 6, please. 24 - - -</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 38	Page 40
<p>1 (Deposition Exhibit No. 2 Lebwohl-6, 9/23/16, 11/18/16, and 3 11/29/16 Invoices from Lebwohl to 4 Slater, was marked for 5 identification.) 6 - - - 7 BY MR. MURPHY: 8 Q. Doctor, you have in front of 9 you what's been marked as Exhibit 7 -- 10 MR. SLATER: These aren't 11 all the invoices I gave you. 12 Right? 13 MR. MURPHY: No, they 14 aren't. 15 MR. SLATER: Because I gave 16 you more. 17 MR. MURPHY: Indeed, you 18 did. 19 THE WITNESS: Can I clarify? 20 This says 6. 21 MR. MURPHY: I'm sorry. 6. 22 I got ahead of myself. 23 BY MR. MURPHY: 24 Q. You have in front of you</p>	<p>1 problem. 2 BY MR. MURPHY: 3 Q. You have in front of you 4 what's been marked as Exhibit 6, which is 5 comprised of three invoices; correct? 6 A. Correct. 7 Q. And the dates on those 8 invoices are September 23, November 18th, 9 and November 29; correct? 10 A. Correct, 2016, all of them. 11 Q. Okay. 12 Now, do these invoices 13 reflect the time and the tasks that you 14 brought to bear in generating your 15 report? 16 A. They are certainly relevant 17 to my generation of the report. 18 Q. Do these invoices reflect 19 all that you billed Mr. Slater for the 20 time spent in generating your report? 21 A. No. 22 Q. Are there other invoices 23 that reflect time that you spent 24 generating your report?</p>
Page 39	Page 41
<p>1 what's been marked as Exhibit 6. These 2 are three invoices that you submitted to 3 Mr. Slater, correct, dated September 4 23rd, November 18, and November 29; 5 correct? 6 MR. SLATER: I think you -- 7 I know what you're doing. I think 8 you missed one, the 28th. If 9 you're just trying to do the 10 general consulting as opposed to 11 the Norman Block case. 12 MR. MURPHY: Right. 13 MR. SLATER: You missed the 14 28th, which I gave you also -- oh, 15 no, no, you're right. You're 16 right. You're good. I just read 17 the body of it. 18 Hey, look, I get to be 19 proven wrong just once. 20 MR. MURPHY: The day's long. 21 I'll restate. 22 THE WITNESS: Yes, please, 23 thank you. 24 MR. MURPHY: That's no</p>	<p>1 A. Not yet, but I'll be sure to 2 make one up. 3 Q. Okay. 4 So as we sit here today, we 5 don't have all of the invoices that you 6 have -- strike that. 7 As we sit here today, you 8 have not billed Mr. Slater for all the 9 time spent in generating your report. 10 A. I've not yet billed Mr. 11 Slater for all the time I spent preparing 12 for this deposition, so perhaps I 13 misspoke. 14 Q. That's not my question. My 15 question is specific to your report. 16 A. With regard to my report, 17 these are the invoices and there are no 18 other invoices out there or forthcoming 19 in terms of generation of this report. 20 Q. Okay. 21 A. I may have misunderstood. 22 Q. No problem. 23 So everything -- all the 24 time associated and all the cost</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 42	Page 44
<p>1 associated with generating your report is 2 reflected in these three invoices; 3 correct? 4 A. Correct. 5 Q. I'll come back to that. 6 I understood you to say that 7 you believe that you started generating 8 this report in late October; is that 9 right? 10 MR. SLATER: Objection. 11 THE WITNESS: I started 12 writing up or typing up the report 13 in late October. 14 BY MR. MURPHY: 15 Q. If you look at Exhibit 6, 16 the first invoice dated -- which is dated 17 September 23, the first entry for time is 18 dated September 11, 2016. 19 Do you see that? 20 A. I do. 21 Q. Is that when you first began 22 working on the report? 23 A. As far as I can remember, 24 that's when I first got into the mode of</p>	<p>1 is not among these two exhibits. 2 Q. So the general -- the 3 general topic as addressed in your 4 report, when did you start working on 5 that? 6 MR. SLATER: Objection; 7 asked and answered. 8 THE WITNESS: I started 9 writing the report in late October 10 and I started working on it in a 11 general manner in September of 12 2016. 13 BY MR. MURPHY: 14 Q. And prior to that time, 15 prior to September of 2016, were there 16 anything -- were there any things that 17 you had done toward that end; that is, 18 prior to 2016, had you done any work 19 related -- 20 MR. SLATER: Objection. You 21 asked this question multiple 22 times. 23 BY MR. MURPHY: 24 Q. -- related to the general</p>
Page 43	Page 45
<p>1 thinking that any materials I was 2 reviewing would now be relevant to a 3 written report. 4 Mr. Slater had me review 5 cases and engage me for discussion and 6 review of the literature before that 7 time, but that was not for concrete 8 preparation for the report, so -- per se, 9 so, yes, in that these activities were 10 the first that were clearly demarcated 11 for preparation of the report. 12 Q. And those other activities 13 that Mr. Slater had asked you to engage 14 in before September 11 of 2016, did you 15 bill him for those? 16 A. Yes. I believe we reviewed 17 those. 18 Q. Would that be what we see 19 reflected in Exhibit 3? 20 A. Yes. 21 Q. So a total of one hour? 22 A. I believe I spent other time 23 discussing specific cases and reviewing 24 -- or certain cases with Mr. Slater that</p>	<p>1 report? 2 MR. SLATER: Objection; 3 asked and answered. 4 You can answer again. 5 THE WITNESS: My 6 communications with Mr. Slater 7 about certain patients were not 8 directly related to this report. 9 MR. MURPHY: Okay. 10 BY MR. MURPHY: 11 Q. Doctor, did any other doctor 12 or any student provide you assistance in 13 generating your report? 14 A. No. 15 Q. So the report is something 16 that you prepared yourself? 17 A. I prepared the report with 18 Mr. Slater. He may have had a student or 19 someone who works with him to help his 20 end of things, but on my end of things, I 21 prepared the work without assistance. 22 Q. Well, you refer to Mr. 23 Slater's end of things -- 24 MR. SLATER: He's not going</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

<p style="text-align: right;">Page 46</p> <p>1 to talk any further about that. 2 That subject's closed. 3 MR. MURPHY: I understand. 4 I'll ask a question and if you 5 want to instruct him not to 6 answer, that's fine, but I will 7 ask the question I want and we'll 8 get beyond that. 9 MR. SLATER: Why don't you 10 ask your question and then we'll 11 see what it actually is, but you 12 know the rule. Right? 13 MR. MURPHY: That's what I'm 14 saying. 15 BY MR. MURPHY: 16 Q. When you refer to Mr. 17 Slater's end of things, what do you mean 18 by that? 19 MR. SLATER: Don't answer. 20 Next question. You're not 21 answering. So, counsel, go to 22 your next question. 23 MR. MURPHY: That's fine. 24 BY MR. MURPHY:</p>	<p style="text-align: right;">Page 48</p> <p>1 offer at trial that are not set forth in 2 this report? 3 MR. SLATER: Objection. 4 You can answer. 5 THE WITNESS: I can't think 6 of anything concrete that is out 7 there that I think is missing with 8 regard to the question at hand. 9 BY MR. MURPHY: 10 Q. Dr. Lebwohl, do you intend 11 to offer any opinions regarding the 12 mechanism by which olmesartan purportedly 13 causes the condition sprue-like 14 enteropathy? 15 MR. SLATER: Objection. 16 You can answer. 17 THE WITNESS: Can you repeat 18 the question? 19 MR. MURPHY: Sure. Would 20 you read it back, Kim? 21 - - - 22 (The court reporter read the 23 pertinent part of the record.) 24 - - -</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. If I can draw your attention 2 to page 43 of your report, in your 3 conclusion section, you write, "there is 4 substantial evidence that, taken on 5 aggregate, establishes the causal 6 relationship between olmesartan and 7 sprue-like enteropathy, to a reasonable 8 degree of medical certainty." 9 That's what you write; 10 correct? 11 A. Correct. 12 Q. If called to trial in this 13 litigation, is that the opinion that you 14 intend to offer? 15 MR. SLATER: Objection. 16 You can answer. 17 THE WITNESS: This is what I 18 believe and if asked if I still 19 believe this question -- this 20 statement, I would respond 21 affirmatively. 22 BY MR. MURPHY: 23 Q. Are there any opinions 24 regarding olmesartan that you intend to</p>	<p style="text-align: right;">Page 49</p> <p>1 THE WITNESS: Yes. 2 BY MR. MURPHY: 3 Q. Have you written any papers 4 on this purported mechanism of action? 5 A. I've certainly written 6 papers that investigate a link between 7 olmesartan use and biological changes 8 that could be relevant to sprue-like 9 enteropathy. 10 MR. MURPHY: Move to strike 11 as nonresponsive. 12 MR. SLATER: Just so know, 13 that doesn't mean it's actually 14 going to happen. He's allowed to 15 place things on the record. 16 MR. MURPHY: As we all do. 17 BY MR. MURPHY: 18 Q. My question to you is 19 whether you have written any papers that 20 address this mechanism of action on which 21 you have an opinion. 22 MR. SLATER: Objection; 23 asked, answered. 24 You can answer it.</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 50	Page 52
<p>1 THE WITNESS: I've certainly</p> <p>2 written about and investigated the</p> <p>3 matter of the clinical phenotype</p> <p>4 seen in patients due to olmesartan</p> <p>5 and a potential organic basis for</p> <p>6 that, in other words, small</p> <p>7 intestinal histologic changes.</p> <p>8 BY MR. MURPHY:</p> <p>9 Q. Have you conducted any</p> <p>10 experiments addressing this purported</p> <p>11 mechanism of action?</p> <p>12 A. I've conducted</p> <p>13 epidemiological experiments.</p> <p>14 Q. Regarding the mechanism of</p> <p>15 action that we're discussing?</p> <p>16 A. Olmesartan-induced</p> <p>17 enteropathy is a clinical diagnosis that</p> <p>18 includes, among other features,</p> <p>19 histologic changes; and the mechanism by</p> <p>20 which olmesartan induces this clinical</p> <p>21 phenotype are histologic changes and I've</p> <p>22 certainly conducted epidemiologic</p> <p>23 experiments in that domain.</p> <p>24 One issue that might be a</p>	<p>1 subject of any papers that you have</p> <p>2 written?</p> <p>3 MR. SLATER: Isn't that the</p> <p>4 question he just answered?</p> <p>5 MR. MURPHY: I want to make</p> <p>6 sure we're clear. We've had</p> <p>7 misunderstandings earlier today.</p> <p>8 MR. SLATER: Objection.</p> <p>9 You can answer.</p> <p>10 THE WITNESS: I must clarify</p> <p>11 what I mean by mechanism, because</p> <p>12 based on the repeated questioning,</p> <p>13 I'm getting the sense that perhaps</p> <p>14 you're referring to a cellular or</p> <p>15 subcellular mechanism.</p> <p>16 I am referring to a more</p> <p>17 broad biological mechanism that</p> <p>18 looks more at organs or systems</p> <p>19 and, yes, I've published in that</p> <p>20 matter.</p> <p>21 BY MR. MURPHY:</p> <p>22 Q. And what articles have you</p> <p>23 published that addressed experiments that</p> <p>24 you conducted on that mechanism of</p>
Page 51	Page 53
<p>1 source of misunderstanding perhaps is</p> <p>2 that mechanisms can refer to molecular or</p> <p>3 subcellular mechanisms, cytokines and</p> <p>4 chemokines, or, beyond the cellular</p> <p>5 level, more of a macroscopic mechanism.</p> <p>6 The biologic mechanism in</p> <p>7 some cases between olmesartan and severe</p> <p>8 diarrhea requiring dehydration would be</p> <p>9 in some cases villous atrophy or other</p> <p>10 histologic changes. That is a biological</p> <p>11 mechanism.</p> <p>12 Q. To the extent that you have</p> <p>13 conducted experiments addressing this</p> <p>14 purported mechanism of action, are they</p> <p>15 addressed in any papers that you have</p> <p>16 written? Those experiments?</p> <p>17 A. I have addressed the</p> <p>18 mechanism -- this mechanism -- in at</p> <p>19 least one such study.</p> <p>20 Q. And just so that we're</p> <p>21 clear, my question to you is focused on</p> <p>22 experiments that you say you've conducted</p> <p>23 addressing the mechanism of action; and</p> <p>24 my question is, are those experiments the</p>	<p>1 action?</p> <p>2 A. I published a paper with Dr.</p> <p>3 Lagana, for example --</p> <p>4 Q. And what is the date, the</p> <p>5 year, of that paper?</p> <p>6 A. This is the paper I'm</p> <p>7 referring to, a "Sprue-like histology in</p> <p>8 patients with abdominal pain taking</p> <p>9 olmesartan compared with other</p> <p>10 angiotensin receptor blockers," published</p> <p>11 in the Journal of Clinical Pathology and</p> <p>12 its publication date was January 2015.</p> <p>13 Q. Any others?</p> <p>14 A. Not that come to mind, no.</p> <p>15 Q. And just so that we're</p> <p>16 clear, it's your testimony that that</p> <p>17 article that you wrote with Dr. Lagana</p> <p>18 addresses experimentation that you</p> <p>19 conducted on the mechanism of action by</p> <p>20 which you say olmesartan causes</p> <p>21 sprue-like enteropathy; correct?</p> <p>22 A. This was a study that</p> <p>23 broadly investigated histologic changes</p> <p>24 among not just olmesartan, but other</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 54	Page 56
<p>1 angiotensin receptor blockers 2 specifically looking for changes that 3 might represent a more subtle histologic 4 finding that had previously been 5 published in the, at that point, 6 still-being-characterized olmesartan 7 enteropathy. 8 MR. MURPHY: I don't think 9 you understood my question. 10 Kim, would you read it back, 11 please? 12 MR. SLATER: You know what? 13 Just for the record, you don't 14 have to say that. 15 MR. MURPHY: No, I -- it is 16 -- 17 MR. SLATER: You can just 18 ask her to reread the question, 19 because, honestly, I think you're 20 not understanding what 21 he's saying. So there's no 22 benefit to you telling him he 23 doesn't understand your question, 24 so let's not do that.</p>	<p>1 you. 2 Are you okay to take a 3 break? 4 MR. SLATER: Sure. Do you 5 need a break? 6 (A recess was taken from 7 10:36 a.m. until 10:46 a.m.) 8 THE WITNESS: Can I add a 9 matter to my recent answer about 10 mechanism of action? 11 MR. MURPHY: Sure. 12 THE WITNESS: I found one 13 other study that I was involved 14 with as a participant, a designer. 15 It was by DeGaetani and 16 colleagues. I'm not sure if I can 17 tell you precisely the title of 18 that paper unless I get lucky and 19 find it in this large binder. 20 MR. SLATER: It's actually 21 not in the Table of Contents. 22 It's right in the beginning, right 23 after the Table of Contents. 24 THE WITNESS: The title of</p>
Page 55	Page 57
<p>1 MR. MURPHY: I don't do 2 that. I don't do that. You've 3 been with me long enough. You 4 know I don't do that. 5 Would you just please read 6 the question back? 7 - - - 8 (The court reporter read the 9 pertinent part of the record.) 10 - - - 11 THE WITNESS: I believe I've 12 answered this in that my 13 understanding of mechanism speaks 14 more broadly than a cellular or 15 molecular basis. 16 We were looking more broadly 17 than that and, yes, in those broad 18 terms, I think it's certainly 19 relevant and can be described as 20 an experiment regarding the 21 mechanism of olmesartan 22 enteropathy and related or more 23 subtle conditions. 24 MR. MURPHY: Okay. Thank</p>	<p>1 the paper is "Villous atrophy and 2 negative serial serology: a 3 diagnostic and therapeutic 4 dilemma." 5 The first author is 6 DeGaetani. The senior author's 7 Peter Green. I was a participant 8 in this study. It was published 9 in the American Journal of 10 Gastroenterology in 2013. 11 BY MR. MURPHY: 12 Q. And that was a paper that 13 addressed an experiment on the mechanism 14 of action that we were talking about; 15 correct? 16 A. Again -- 17 MR. SLATER: Objection. 18 You can answer. 19 THE WITNESS: Again, when -- 20 when contemplating mechanism by 21 which olmesartan causes this 22 clinical phenotype, this is an 23 experiment in that domain. 24 MR. MURPHY: Okay.</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

<p style="text-align: right;">Page 58</p> <p>1 BY MR. MURPHY:</p> <p>2 Q. Your report -- in your</p> <p>3 report, you identify yourself as a</p> <p>4 gastroenterologist; correct?</p> <p>5 A. I am a gastroenterologist.</p> <p>6 Q. Are you a pathologist?</p> <p>7 A. I am not a pathologist,</p> <p>8 though I frequently participate in</p> <p>9 clinicopathologic conferences and I have</p> <p>10 frequent interactions with pathologists</p> <p>11 as part of my day-to-day clinical and</p> <p>12 research life.</p> <p>13 Q. Are you a toxicologist?</p> <p>14 A. I am not a toxicologist,</p> <p>15 though I've interacted with toxicologists</p> <p>16 in terms of clinical and teaching</p> <p>17 responsibilities and I've certainly</p> <p>18 studied potential adverse effects of</p> <p>19 medications.</p> <p>20 Q. You have some training in</p> <p>21 epidemiology; is that right?</p> <p>22 A. I practice epidemiology. I</p> <p>23 conduct epidemiological research. I'm on</p> <p>24 the faculty in the department of</p>	<p style="text-align: right;">Page 60</p> <p>1 I would add that animal</p> <p>2 studies are most helpful in preclinical</p> <p>3 testing and they are most helpful in the</p> <p>4 absence of any clinical data; and,</p> <p>5 unfortunately, we now have a large amount</p> <p>6 of data about human beings who've been</p> <p>7 harmed by olmesartan.</p> <p>8 Q. In the conclusion section of</p> <p>9 your report that we looked at a moment</p> <p>10 ago, you wrote in part that there is</p> <p>11 substantial evidence that, quote, taken</p> <p>12 on aggregate, establishes this causal</p> <p>13 relationship.</p> <p>14 When you write "taken on</p> <p>15 aggregate," do you mean taken as a whole?</p> <p>16 A. What I mean by taken on</p> <p>17 aggregate is just that; but if you'd like</p> <p>18 me to clarify, it's that it's more than</p> <p>19 one single study, more than one single</p> <p>20 case that provides the convincing</p> <p>21 evidence of this causal relationship;</p> <p>22 it's the aggregate or the collection of</p> <p>23 these data.</p> <p>24 Q. Is -- are there studies and</p>
<p style="text-align: right;">Page 59</p> <p>1 epidemiology at Mailman School of Public</p> <p>2 Health, and so I am an epidemiologist.</p> <p>3 Q. But you're not a biologist.</p> <p>4 A. That's a term we don't</p> <p>5 really use so much in clinical research</p> <p>6 or epidemiological research; but if you</p> <p>7 mean colloquially the notion of someone</p> <p>8 who performs in vitro studies with</p> <p>9 pipettes and tissue cultures, that is not</p> <p>10 my day to day or -- focus.</p> <p>11 Q. I understand.</p> <p>12 Dr. Lebwohl, have you read</p> <p>13 any articles that indicate or suggest</p> <p>14 that olmesartan causes inflammation in</p> <p>15 the intestine of animals?</p> <p>16 A. I am not deeply acquainted</p> <p>17 with the animal literature on olmesartan</p> <p>18 except for what I would argue is the most</p> <p>19 relevant animal, humans.</p> <p>20 Q. So you're not familiar with</p> <p>21 the animal studies.</p> <p>22 A. I do not have a deep</p> <p>23 familiarity with animal studies relating</p> <p>24 to olmesartan.</p>	<p style="text-align: right;">Page 61</p> <p>1 data to the contrary that you're aware</p> <p>2 of?</p> <p>3 A. I'm not aware of any</p> <p>4 published studies that dispute causality.</p> <p>5 In fact, this is now an entity that's</p> <p>6 being increasingly recognized around the</p> <p>7 world.</p> <p>8 And until I read expert</p> <p>9 reports from the defendants' side and</p> <p>10 until I started reviewing depositions, I</p> <p>11 had no idea that there were people who</p> <p>12 denied the existence of olmesartan</p> <p>13 enteropathy.</p> <p>14 Q. Your review of defendants'</p> <p>15 reports was something that you engaged in</p> <p>16 after you wrote your report; correct?</p> <p>17 A. To the best of my</p> <p>18 recollection, correct.</p> <p>19 Q. Is it your opinion, Dr.</p> <p>20 Lebwohl, that all medical literature on</p> <p>21 the subject indicates that olmesartan</p> <p>22 causes sprue-like enteropathy?</p> <p>23 A. I would say that there is no</p> <p>24 convincing published literature that puts</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 62	Page 64
<p>1 forth that olmesartan does not cause 2 enteropathy or the olmesartan enteropathy 3 clinical phenotype. There are certainly 4 studies that have nothing to do with 5 olmesartan enteropathy that are in the 6 published literature. There are also 7 studies of olmesartan that do not 8 specifically investigate olmesartan 9 enteropathy. There are also studies that 10 are post hoc analyses of previous 11 experiments that were not powered or 12 predestined -- or predesigned, rather -- 13 to investigate olmesartan enteropathy, 14 and those are in the literature.</p> <p>15 But there are no convincing 16 studies that essentially deny the 17 existence of olmesartan enteropathy, nor 18 can I even find an editorial or opinion 19 piece in the published literature by any 20 expert in the field that suggests that 21 olmesartan does not, in a subset of 22 individuals, cause olmesartan 23 enteropathy.</p> <p>24 Q. Were there reports or</p>	<p>1 prohibitively expensive given what we now 2 know about the time course and what we're 3 increasingly learning about the incidence 4 of olmesartan enteropathy.</p> <p>5 I believe a randomized trial 6 would probably be a lousy way to 7 investigate olmesartan enteropathy.</p> <p>8 MR. MURPHY: Move to strike 9 everything after "if anyone asked 10 me."</p> <p>11 BY MR. MURPHY:</p> <p>12 Q. Doctor, with regard to the 13 time course that you referenced, what is 14 the time course to onset?</p> <p>15 A. Is that the end of your 16 question?</p> <p>17 Q. That's the end of my 18 question and if you don't know what I 19 mean by that, I'm happy to rephrase the 20 question.</p> <p>21 A. The time course from onset 22 to diagnosis can be quite long, 23 particularly relating to the relative 24 lack of knowledge in the community of</p>
Page 63	Page 65
<p>1 articles that you read that specifically 2 addressed that question, that is, whether 3 olmesartan causes sprue-like enteropathy 4 in a subset of individuals?</p> <p>5 MR. SLATER: Objection. 6 You can answer.</p> <p>7 THE WITNESS: I think that 8 the bulk of literature on the 9 subject of olmesartan enteropathy 10 addresses this question of 11 whether, in a subset of 12 individuals, olmesartan causes 13 sprue-like enteropathy.</p> <p>14 BY MR. MURPHY:</p> <p>15 Q. And how many randomized 16 controlled trials address this issue that 17 you're aware of?</p> <p>18 A. To my knowledge, there have 19 been zero randomized controlled trials 20 designed to investigate the outcome of 21 olmesartan enteropathy; and, frankly, if 22 anyone approached me with -- asking my 23 advice about designing such a study, I 24 would have told them it would be</p>	<p>1 olmesartan enteropathy. Patients can 2 suffer for prolonged periods of time, 3 typically months, but perhaps longer, 4 years even, and I would also say that the 5 time course has been quite variable.</p> <p>6 Q. And with regard to that last 7 point, the variable time course, there 8 are case reports, in fact you've referred 9 to, where the time course has been less 10 than a year; correct?</p> <p>11 A. There have been reports of 12 olmesartan causing enteropathy in a time 13 course of under one year.</p> <p>14 Q. And the fact that the time 15 course in certain instances is more than 16 two years suggests that there might be 17 other environmental factors that are 18 causing the enteropathy; correct?</p> <p>19 A. I would say more than in 20 some instances. If -- allow me, please, 21 to look at the first case series by 22 Rubio-Tapia and colleagues.</p> <p>23 (Pause.)</p> <p>24 THE WITNESS: In the study</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 66	Page 68
<p>1 by Rubio-Tapia and colleagues, the 2 mean duration of olmesartan use 3 was actually 3.1 years, with a 4 range reported of .5 years, in 5 other words about six months, to 6 seven years.</p> <p>7 Now, you were asking about 8 whether that is related to a 9 hypothesized mechanism?</p> <p>10 MR. MURPHY: No.</p> <p>11 Kim, would you read my 12 question back, please?</p> <p>13 - - -</p> <p>14 (The court reporter read the 15 pertinent part of the record.)</p> <p>16 - - -</p> <p>17 THE WITNESS: No. First of 18 all, it's not in some instances. 19 It seems to be often if not 20 perhaps the majority of instances 21 as far as we know, but the fact 22 that this does appear to be a -- 23 more of a long-term adverse effect 24 suggests that this is not an acute</p>	<p>1 atrophy and the cause of that is gluten.</p> <p>2 And yet the onset of not 3 just symptoms, but villous atrophy, in 4 celiac disease can occur as young as 5 first year of life when gluten is first 6 introduced, but often can happen years 7 later, even in -- even in adulthood. It 8 doesn't mean that it was something else 9 that was responsible for the celiac 10 disease. It's clearly gluten that is the 11 cause.</p> <p>12 In epidemiology, we 13 sometimes use the term "causal pies" when 14 discussing causality and it's a metaphor. 15 If you've ever played the game Trivial 16 Pursuit, the notion that you win the game 17 when you've filled out the entire pie, 18 olmesartan is what is necessary for 19 developing olmesartan enteropathy, but it 20 might not be sufficient. There might be 21 some other factors that need to be 22 present.</p> <p>23 So we don't yet know what 24 those factors are, but one can speculate,</p>
Page 67	Page 69
<p>1 allergic reaction.</p> <p>2 It suggests that there does 3 appear to require either some sort 4 of cumulative effect of damage or 5 some sort of priming of the immune 6 system or some cofactor that 7 perhaps was not present during -- 8 at the beginning or onset of 9 olmesartan use, but with long 10 enough time of exposure of 11 olmesartan, that as yet 12 unidentified cofactor could be 13 triggering olmesartan's induction 14 of enteropathy.</p> <p>15 BY MR. MURPHY:</p> <p>16 Q. Is it your --</p> <p>17 A. If I could just finish.</p> <p>18 Q. I'm sorry. I didn't know 19 you were...</p> <p>20 A. So celiac disease in certain 21 ways provides an analogous situation. 22 People with celiac disease develop 23 symptoms, and the biologic mechanism for 24 the symptoms in many patients is villous</p>	<p>1 for example, someone taking olmesartan 2 for years, but then has some breakdown in 3 the gut barrier that allows olmesartan to 4 encounter components of the immune system 5 that it had not previously been exposed 6 to, so a gastroenteritis or some other 7 cofactor, and only when that happens does 8 the patient develop olmesartan 9 enteropathy.</p> <p>10 This is -- this strikes me 11 as one plausible way to explain why 12 olmesartan doesn't cause enteropathy in 13 everyone, but only in some individuals 14 who have those other cofactors or who 15 develop those cofactors over time.</p> <p>16 Q. So is it your -- your 17 testimony, Doctor, that, in your view, 18 olmesartan causes sprue-like enteropathy 19 in individuals in different ways?</p> <p>20 A. I would say that it causes 21 enteropathy in a subset of individuals, 22 and the clinical manifestations and 23 laboratory and histologic manifestations 24 can vary.</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 70	Page 72
<p>1 Q. So with regard to an 2 individual who presents with enteropathy 3 after olmesartan therapy compared to an 4 individual who develops enteropathy after 5 olmesartan therapy after two years, is it 6 your understanding that olmesartan 7 affects those two individuals similarly?</p> <p>8 MR. SLATER: Objection. 9 You can answer.</p> <p>10 THE WITNESS: You know, the 11 first hypothetical you provided 12 didn't specify a time course. I 13 think -- and perhaps you could 14 read back the question, the first 15 half of the -- of that question. 16 - - -</p> <p>17 (The court reporter read the 18 pertinent part of the record.) 19 - - -</p> <p>20 THE WITNESS: So that's 21 somewhat vague --</p> <p>22 MR. MURPHY: Less than a 23 year. So with regard to an 24 individual who presents with</p>	<p>1 those two and that the major 2 differences between someone who 3 presents late and someone who 4 presents early could be related to 5 the development of whatever that 6 unidentified cofactor is.</p> <p>7 But even getting beyond 8 biology, there could be social 9 differences. For example, someone 10 could have the unfortunate 11 experience -- and I've certainly 12 seen such cases -- of a patient 13 going from doctor to doctor, 14 including gastroenterologists, and 15 being misdiagnosed again and again 16 until finally someone who was 17 familiar with the clinical entity 18 of olmesartan enteropathy makes 19 the diagnosis.</p> <p>20 Someone else who is luckier, 21 though still unlucky because he or 22 she has this syndrome, might get 23 it more promptly recognized 24 because they were in an area or in</p>
Page 71	Page 73
<p>1 enteropathy incident to olmesartan 2 therapy in less than a year --</p> <p>3 THE WITNESS: Do you mean 4 due to olmesartan therapy?</p> <p>5 MR. MURPHY: No. An 6 individual who is taking 7 olmesartan and they then present 8 with symptoms of enteropathy.</p> <p>9 THE WITNESS: While still 10 taking the olmesartan regularly or 11 intermittently or what have you?</p> <p>12 MR. MURPHY: Yes -- in less 13 than one year, comparing that 14 individual to someone who does not 15 present with enteropathy while on 16 olmesartan therapy until two years 17 or more, my question to you is, 18 does the olmesartan -- in your 19 view, does the olmesartan cause 20 the enteropathy in the same way?</p> <p>21 THE WITNESS: I don't think 22 we know enough to be sure yes or 23 no. It's very possible that there 24 are very similar features between</p>	<p>1 an institution or had a provider 2 or knew someone who was more 3 familiar with the entity.</p> <p>4 We have great experience in 5 this regard in the world of celiac 6 disease. There has been, you 7 know, a real spectrum of duration 8 of symptoms prior to diagnosis and 9 this is due to another -- a number 10 of factors; but even for celiac 11 disease, in which gluten triggers 12 enteropathy in the susceptible 13 individuals, there are people who 14 go to multiple doctors and don't 15 get recognized, and so there's 16 certainly a wide variation.</p> <p>17 Sometimes these two clinical 18 phenotypes are very similar. It's 19 just that one person suffered for 20 longer before she got diagnosed. 21 Sometimes the phenotypes are 22 different.</p> <p>23 BY MR. MURPHY: 24 Q. You mentioned similarities</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 74	Page 76
<p>1 between celiac disease and sprue-like 2 enteropathy. With regard to the 3 histological or histologic presentations 4 or manifestations of celiac disease, are 5 they similar to the histologic 6 presentation of one who is suffering from 7 sprue-like enteropathy?</p> <p>8 A. Histologically, celiac 9 disease and olmesartan enteropathy share 10 some features, which is an explanation 11 for the phenomenon we've observed where 12 many people with olmesartan enteropathy 13 are initially misdiagnosed with celiac 14 disease.</p> <p>15 Q. Olmesartan doesn't cause 16 celiac disease, does it?</p> <p>17 A. That's an interesting 18 question. In the case series by 19 Rubio-Tapia, a proportion of patients had 20 been initially diagnosed with celiac 21 disease.</p> <p>22 (Pause.)</p> <p>23 THE WITNESS: They state 24 that the cause of the enteropathy</p>	<p>1 That said, I am not sure 2 that they are only related in that 3 one looks like the other. It is 4 possible that someone with celiac 5 disease could then develop 6 olmesartan enteropathy and it is 7 also possible that olmesartan 8 enteropathy can occur and a 9 patient subsequently develops 10 celiac disease and, related to 11 that, it's possible that 12 olmesartan could even trigger 13 celiac disease.</p> <p>14 I would say the jury's not 15 out on that and it is in need of 16 further study.</p> <p>17 BY MR. MURPHY:</p> <p>18 Q. Did you mean that the jury 19 is out on that, that is, the jury hasn't 20 spoken on that question; is that what you 21 mean to say?</p> <p>22 A. Why don't I rephrase.</p> <p>23 Q. That's fine.</p> <p>24 A. Because I probably have the</p>
Page 75	Page 77
<p>1 could not be established and then 2 it goes on to say for disorders 3 associated -- that included -- 4 included investigation for 5 disorders associated with 6 nonresponsive celiac disease.</p> <p>7 And so those patients had 8 initially been misdiagnosed with 9 celiac disease and, indeed, when 10 you look at the subsequent 11 literature of the case reports 12 that have come up from around the 13 world, often, patients are 14 initially misdiagnosed with celiac 15 disease.</p> <p>16 Indeed, an epidemiologic 17 study by Basson and colleagues 18 looked at celiac disease as a 19 secondary outcome because of and 20 informed by this phenomenon of 21 people initially being 22 misdiagnosed with celiac disease. 23 And so they are closely related in 24 that -- in that way.</p>	<p>1 least legal expertise in the room.</p> <p>2 MR. SLATER: Don't be sure 3 about that.</p> <p>4 THE WITNESS: The matter has 5 not been decided upon.</p> <p>6 BY MR. MURPHY:</p> <p>7 Q. So my question was whether 8 olmesartan causes celiac disease and my 9 -- my sense of your answer is, it's 10 unknown?</p> <p>11 A. I would say, first of all, 12 that I was not asked to formulate an 13 opinion on that for the purposes of 14 today's deposition, but what I would say 15 is that we don't know.</p> <p>16 Q. And with regard to the 17 Rubio-Tapia paper that you were referring 18 to, wasn't it the case that part of the 19 inclusion criteria was that participants 20 had to be -- had to rule out celiac?</p> <p>21 A. Let's take a look.</p> <p>22 Their inclusion criteria 23 included that the cause of their 24 enteropathy could not be established</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 78	Page 80
<p>1 after systematic diagnostic evaluation 2 that included investigation for disorders 3 associated with nonresponsive celiac 4 disease. And their second criteria -- 5 criterion is that they had to improve 6 clinically after discontinuation of drug. 7 Q. Okay. 8 And so my -- I guess my 9 follow-on question to you is, were the 10 Rubio-Tapia participants assumed not to 11 be suffering from celiac disease? 12 A. Ultimately, yes, in fact, 13 the authors' comment, no patient had 14 recurrence of symptoms after restarting a 15 gluten-containing diet. 16 Our understanding of celiac 17 disease today is that celiac disease 18 doesn't go away. There have been very 19 rare documented reports of something 20 called transient celiac autoimmunity, but 21 in general, celiac disease is a lifelong 22 diagnosis and that gluten causes 23 recurrence of the abnormalities. 24 And so these authors</p>	<p>1 MR. MURPHY: That would be 2 Exhibit 2 to your report. 3 MR. SLATER: The last thing 4 you want to rely on is the Table 5 of Contents my office did, which 6 is incomplete. 7 THE WITNESS: Thank you 8 both, gentlemen. Give me a 9 moment. 10 (Pause.) 11 THE WITNESS: Okay. I'm 12 there. 13 BY MR. MURPHY: 14 Q. In your reliance list, you 15 identify certain deposition transcripts 16 that you reviewed; correct? 17 A. Correct. 18 Q. And the first one you 19 identify is Allen Feldman? 20 A. Yes. 21 Q. And on the next page, you 22 identify Donald Hinman. It's on page 2 23 of your -- if we have the same document. 24 MR. SLATER: Right there</p>
Page 79	Page 81
<p>1 concluded that these patients in this 2 case series did not have celiac disease. 3 Q. And one of the reasons they 4 concluded that was because they were 5 exposed to gluten or reexposed to gluten 6 and there was no change. 7 A. That's one of the reasons. 8 Also, they do make allusion to the 9 systematic evaluation that included 10 investigations for disorders associated 11 with nonresponsive celiac disease and had 12 not come up with an alternative plausible 13 explanation and, third, these patients 14 were better once the cause was 15 identified, olmesartan. 16 Q. Let me direct your attention 17 to your report and in particular your 18 reliance list. Are you there? 19 A. Yes. 20 MR. SLATER: No, you're not. 21 You said the reliance list? 22 MR. MURPHY: In his report. 23 MR. SLATER: Yeah, you gotta 24 go to your report.</p>	<p>1 (Indicating). 2 THE WITNESS: Thank you. 3 Yes, thank you. 4 BY MR. MURPHY: 5 Q. Below Mr. Hinman is Yasushi 6 Hasebe. Do you see that at the bottom of 7 page 2? 8 A. Hasebe? 9 Q. Yes. 10 A. Yes. 11 Q. And on the next page, you 12 identify Hideki Tagawa. 13 A. Yes. 14 Q. Page 4, Jeffrey Warmke? 15 A. Yes, I see that. 16 Q. Page 6, Herve Caspard; 17 correct? 18 A. Yes. 19 Q. And if you go to page 8, 20 Crawford Parker is another deposition 21 that you reviewed; correct? 22 A. Yes. 23 Q. If you go to page 11, at the 24 bottom of page 11, Tina Ho is a witness</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 82	Page 84
<p>1 whose deposition you reviewed; correct?</p> <p>2 A. Correct.</p> <p>3 Q. Do you know how many Daiichi</p> <p>4 company witnesses were deposited in this</p> <p>5 litigation?</p> <p>6 A. I do not.</p> <p>7 Q. But you -- are you aware</p> <p>8 that you have not reviewed them all?</p> <p>9 A. I review what Adam Slater</p> <p>10 shows me and so I'm really not sure.</p> <p>11 Q. The depositions that you did</p> <p>12 review, your review of those depositions,</p> <p>13 was that work for which you charged Mr.</p> <p>14 Slater?</p> <p>15 A. The depositions that I read</p> <p>16 carefully, word for word, and closely, I</p> <p>17 believe are enumerated in my invoices. I</p> <p>18 did read through the other ones, but it's</p> <p>19 possible, first, that I didn't invoice if</p> <p>20 it was brief.</p> <p>21 Q. So there may be some</p> <p>22 transcripts that you reviewed that are</p> <p>23 not reflected in an invoice; is that</p> <p>24 right?</p>	<p>1 A. I have it.</p> <p>2 Q. For the invoice for</p> <p>3 September 23, among other things, you</p> <p>4 identify the deposition review of Allen</p> <p>5 Feldman; correct?</p> <p>6 A. Can you tell me the date</p> <p>7 again?</p> <p>8 Q. Sure. September 23, 2016.</p> <p>9 A. Oh, on that invoice, yes.</p> <p>10 Q. You also have or identified</p> <p>11 a review of deposition of Hideki Tagawa.</p> <p>12 A. Yes. I should clarify. It</p> <p>13 says September 23, 2015. That was meant</p> <p>14 to be 2016. I think it's obvious.</p> <p>15 Q. Okay.</p> <p>16 And if we look at the next</p> <p>17 invoice under exhibit -- or in Exhibit 6</p> <p>18 --</p> <p>19 A. Yes.</p> <p>20 Q. -- there are no deposition</p> <p>21 reviews identified there; correct?</p> <p>22 A. It is correct that none were</p> <p>23 explicitly named, but it's very possible</p> <p>24 that the documents that I reviewed during</p>
Page 83	Page 85
<p>1 MR. SLATER: You mean --</p> <p>2 when you say not reviewed, you</p> <p>3 mean names. Right?</p> <p>4 MR. MURPHY: Pardon me?</p> <p>5 MR. SLATER: You're asking</p> <p>6 whether the person was named in an</p> <p>7 invoice. Right?</p> <p>8 MR. MURPHY: Correct.</p> <p>9 THE WITNESS: Not all of the</p> <p>10 depositions on this reliance list</p> <p>11 are named in my invoices and that</p> <p>12 reflects the depth at which I</p> <p>13 spent time reviewing the</p> <p>14 depositions.</p> <p>15 BY MR. MURPHY:</p> <p>16 Q. So if not identified in an</p> <p>17 invoice, had not reviewed in depth; is</p> <p>18 that what you're saying?</p> <p>19 A. Not reviewed in depth to the</p> <p>20 degree that, for example, the ones that I</p> <p>21 did invoice for.</p> <p>22 Q. I'm going to ask you to take</p> <p>23 a look at Exhibit 6 you have in front of</p> <p>24 you.</p>	<p>1 that time for which I invoiced included</p> <p>2 some of those brief reviews of those</p> <p>3 other depositions.</p> <p>4 Q. And if we turn to the third</p> <p>5 page of Exhibit 6, that is your invoice</p> <p>6 dated November 29; correct?</p> <p>7 A. I see it, yes.</p> <p>8 Q. That document does not</p> <p>9 reference review of any deposition</p> <p>10 transcripts; correct?</p> <p>11 A. It does not, but I believe I</p> <p>12 probably looked at depositions, either</p> <p>13 ones that I had previously reviewed so as</p> <p>14 to refresh in preparation of my report or</p> <p>15 some of those other ones that are on the</p> <p>16 reliance list.</p> <p>17 Q. So just so that we're clear,</p> <p>18 there is no reference to -- in your bills</p> <p>19 or your invoices, no reference to review</p> <p>20 of Mr. Warmke's or Dr. Warmke's</p> <p>21 deposition; correct?</p> <p>22 A. He is not named on the</p> <p>23 invoice.</p> <p>24 Q. Okay. Nor is Dr. Hinman;</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 86	Page 88
<p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. Nor is Tina Ho.</p> <p>4 A. That's correct, she's not</p> <p>5 mentioned in the invoices.</p> <p>6 Q. And nor is Herve Caspard.</p> <p>7 A. That is correct.</p> <p>8 Q. In your reliance list that</p> <p>9 accompanies your report, you identify the</p> <p>10 expert report of Steven M. Lagana as</p> <p>11 something that you relied upon; is that</p> <p>12 right?</p> <p>13 A. I'm just going to go back to</p> <p>14 my reliance list.</p> <p>15 Q. You can look at the end, on</p> <p>16 page 21 of your report, so that you see</p> <p>17 what I'm referring to.</p> <p>18 A. I see it.</p> <p>19 Q. So you identified Dr.</p> <p>20 Lagana's report as something that you</p> <p>21 relied upon.</p> <p>22 A. Yes.</p> <p>23 Q. To what extent do you rely</p> <p>24 on his report to reach your opinion?</p>	<p>1 question? I object. Asked and</p> <p>2 answered.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: Well, I found</p> <p>5 that Dr. Lagana's report gave</p> <p>6 additional supporting, helpful</p> <p>7 information, primarily from a</p> <p>8 histopathologic perspective, which</p> <p>9 I did not deeply address, but that</p> <p>10 he did -- or I should clarify,</p> <p>11 that I did not address as in depth</p> <p>12 as he did.</p> <p>13 - - -</p> <p>14 (Deposition Exhibit No.</p> <p>15 Lebwohl-7, Document Entitled "In</p> <p>16 re: Benicar (Olmesartan) Products</p> <p>17 Liability Litigation Supplemental</p> <p>18 Reliance List for Dr. Benjamin</p> <p>19 Lebwohl", was marked for</p> <p>20 identification.)</p> <p>21 - - -</p> <p>22 BY MR. MURPHY:</p> <p>23 Q. Doctor, you have in front of</p> <p>24 you what's been marked as Exhibit 7 to</p>
Page 87	Page 89
<p>1 A. Well, I read his report and</p> <p>2 found that it was largely congruent with</p> <p>3 my report. Dr. Lagana's area of</p> <p>4 expertise, while like mine, is olmesartan</p> <p>5 enteropathy, among other areas. His</p> <p>6 report was more of a histopathological</p> <p>7 discussion and I found it helpful,</p> <p>8 because I felt that it complemented my</p> <p>9 report, which focused more on the</p> <p>10 clinical and epidemiological aspects of</p> <p>11 this condition.</p> <p>12 Q. Without the benefit of Dr.</p> <p>13 Lagana's report, do you still reach the</p> <p>14 opinion set forth in your conclusion?</p> <p>15 A. If there were no other</p> <p>16 expert reports on this matter, including</p> <p>17 Dr. Lagana's report, so if Dr. Lagana's</p> <p>18 report had not been written, I would</p> <p>19 still have reached the same conclusion</p> <p>20 regarding causality.</p> <p>21 Q. So to what extent do you</p> <p>22 rely on Dr. Lagana's report?</p> <p>23 MR. SLATER: I'm sorry.</p> <p>24 Didn't he just answer that</p>	<p>1 your deposition and it is a supplemental</p> <p>2 reliance list for Dr. Benjamin Lebwohl.</p> <p>3 This is a document that was provided to</p> <p>4 us by Mr. Slater yesterday.</p> <p>5 Is this your supplemental</p> <p>6 reliance list?</p> <p>7 A. Yes.</p> <p>8 Q. Now, the materials that we</p> <p>9 saw reflected in Exhibit 2 to your</p> <p>10 report, including the reference to the</p> <p>11 depositions and the various pieces of</p> <p>12 literature, are -- and Dr. Lagana's</p> <p>13 report, am I correct that those are all</p> <p>14 of the things that you relied upon to</p> <p>15 reach the conclusion that we saw</p> <p>16 reflected at the conclusion -- I'm sorry</p> <p>17 -- reach the opinion that we saw</p> <p>18 reflected in the conclusion of your</p> <p>19 report?</p> <p>20 MR. SLATER: Objection.</p> <p>21 You can answer.</p> <p>22 THE WITNESS: I believe we</p> <p>23 went over this earlier when I</p> <p>24 related that there are certainly</p>

Page 90	Page 92
<p>1 aspects of my clinical experience 2 and my background and course work 3 that I took, if you recall. 4 If you'd like, we could read 5 that answer back. Maybe that 6 would suffice or I could repeat it 7 or paraphrase it again. 8 BY MR. MURPHY: 9 Q. Just so that we are clear, I 10 understand fully that part and parcel of 11 what you bring to an opinion is your 12 background and experience. 13 We here are talking about a 14 reliance list that is identified in 15 enumerated items that you have relied 16 upon and that is what constitutes Exhibit 17 2 to your report, a list of articles, a 18 list of depositions, and an expert report 19 that you relied upon in reaching your 20 opinion; correct? 21 MR. SLATER: Objection. 22 You can answer. 23 THE WITNESS: Exhibit 2 was 24 the plaintiffs' --</p>	<p>1 causal pies was not something that's in 2 my reliance list, but is well established 3 in epidemiology. 4 Q. The medical literature that 5 is identified in Exhibit 7, the 6 supplemental reliance list -- 7 A. I see it. 8 Q. -- that medical literature 9 was -- that list of literature was not 10 something that you relied upon to 11 generate your report and your opinion; 12 correct? 13 MR. SLATER: Objection. 14 You can answer. 15 THE WITNESS: I'm sorry. 16 There are several negatives in 17 that question, so I'm not sure -- 18 MR. MURPHY: That's fine. 19 BY MR. MURPHY: 20 Q. The list of medical 21 literature runs from 1 to 23. Do you see 22 that? 23 A. I do. 24 Q. Those articles listed, 1 to</p>
Page 91	Page 93
<p>1 MR. MURPHY: No, Exhibit 2 2 to your report. 3 THE WITNESS: Oh, 4 understood. 5 Can you repeat the question? 6 I'm sorry. 7 MR. MURPHY: Sure. Sure, I 8 can. 9 BY MR. MURPHY: 10 Q. Exhibit 2 to your report 11 called a reliance list identifies the 12 things and the items of information, 13 including articles, expert reports, 14 deposition transcripts, that you rely 15 upon in reaching your opinion; correct? 16 A. This is my reliance list and 17 this is what I relied upon in terms of 18 the available documents, published 19 literature, et cetera, in formulating my 20 opinion, with the proviso that I said 21 previously: That sometimes it's helpful 22 to bring up well-established ideas when 23 they come up in a helpful way. 24 I would say, for example,</p>	<p>1 23, were they articles that you relied 2 upon when you initially generated your 3 report? 4 A. I can't say there was one 5 that was a linchpin, especially at the 6 time that, for example, I was first 7 writing the report. 8 I can think of some that 9 have come up while I was generating the 10 report, but perhaps not explicitly or not 11 in detail, and only subsequently did we 12 realize this belongs on a reliance list. 13 Q. And so my -- my next 14 question to you is, why were these 15 medical articles not included on your 16 initial reliance list? 17 A. Well, we could go through 18 them if you'd like. There were -- for 19 example, Julian Abrams and colleagues, 20 "Seronegative celiac disease: increased 21 prevalence with lesser degrees of villous 22 atrophy," this is something I was -- that 23 I was aware of. I'm a colleague of Dr. 24 Abrams', but it was, shall we say, in the</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 94	Page 96
<p>1 back of my mind and not explicitly in the 2 fore of things when I was preparing this 3 report, but only in subsequent review or 4 in further discussion with Mr. Slater or 5 in review of subsequent depositions did I 6 realize, well, this is relevant, we 7 should put this in.</p> <p>8 For Padwal and colleagues, 9 this was a study that I had minimal or 10 very vague recollection of at the time 11 that I wrote the report, and only when I 12 saw that it was cited in other reports 13 did I realize this really should be 14 something that I should comment on or 15 take into account.</p> <p>16 And I can go over some 17 others if you'd like. So --</p> <p>18 Q. Well, let me -- I'm sorry. 19 A. For example -- 20 Q. Go ahead. 21 A. -- let me just finish -- I 22 believe Uehara and colleagues was a case 23 report that I was not aware of until 24 after I completed my report and only</p>	<p>1 specifically, I'm fairly confident that I 2 didn't know about that paper until I 3 wrote the report, but I'd have to 4 double-check.</p> <p>5 Q. Are there any others that 6 you can identify that you were unaware of 7 at the time that you wrote your report?</p> <p>8 A. Well, I can give you an 9 example. It depends what you mean by 10 unaware --</p> <p>11 Q. Well, it's your terms, it's 12 your term.</p> <p>13 A. -- so I'll say that by 14 unaware, for example, Stephen Lagana in 15 reference number 23, "Angiotensin 16 Receptor Blockers Other than Olmesartan 17 Are Not Associated with Histologic 18 Evidence of Duodenitis" Annual Meetings 19 Abstract, that eventually was further 20 developed and made its way into a 21 publication that is on my reliance list, 22 but only after this abstract presentation 23 was specifically discussed in a 24 deposition did I realize that perhaps</p>
Page 95	Page 97
<p>1 noted it subsequently.</p> <p>2 So I would say we can't 3 generalize about why each of these made 4 it in. I would say those are probably 5 the big baskets, background knowledge 6 that I assume people take for granted -- 7 there's something called the curse of 8 knowledge where you assume that the 9 person you're talking to has the same 10 background in terms of experience, but, 11 of course, in this situation, we 12 shouldn't assume that and so some of 13 those made it in that way.</p> <p>14 But these other baskets are, 15 I wasn't aware it existed or I was only 16 dimly aware and only after subsequent 17 review of documents did I realize this is 18 relevant.</p> <p>19 Q. So for certain of these 20 articles listed in your supplemental 21 report, you simply were unaware of them 22 at the time that you generated your 23 report; correct? 24 A. I think for Uehara</p>	<p>1 that version of it should be on it.</p> <p>2 I certainly remember when we 3 developed that abstract and I remember 4 presenting it, but at the time of 5 developing my report, I didn't remember 6 it at the time.</p> <p>7 Q. And then there are -- well, 8 before I ask that question, are there any 9 others that you were unaware of at the 10 time that you wrote your report?</p> <p>11 MR. SLATER: Objection. 12 You can answer. 13 BY MR. MURPHY: 14 Q. Have we exhausted that list? 15 A. I'm not sure if I knew about 16 the paper by Al-Bawardy and colleagues, 17 reference number 8, "Collagenous sprue 18 cross-sectional imaging: a comparative 19 blinded study." 20 I am aware of this study. 21 I'm not sure when it first popped into 22 PubMed, for example. I do see that it 23 has the date January 5th, 2017, so it's 24 very possible that it hadn't been out</p>

<p style="text-align: right;">Page 98</p> <p>1 there at the time that I wrote my report. 2 I think that would be a helpful hint. 3 I would say I was -- Padwal 4 and colleagues I think I gave as an 5 example of something that really was not 6 something that I -- was in the forefront 7 of my recollection and I remember seeing 8 it noted and asking myself, have I seen 9 this, and then I had to look at it again 10 and it sort of jogged my memory. I think 11 that chalk that one up to search engine 12 optimization. It's not something that 13 mentions olmesartan in its title, so it 14 could have been that I missed it when 15 doing a literature review. 16 I think that -- I'm pretty 17 sure that number 19, Gujral and 18 colleagues, was an article that I was not 19 specifically aware of at the time that I 20 generated my report, but actually went 21 back, because there was a statement in 22 one of the expert reports that I thought 23 -- that I took an issue with that 24 suggested that it's irrelevant to study</p>	<p style="text-align: right;">Page 100</p> <p>1 yes, my recollection was -- was 2 stimulated by seeing these mentioned in 3 either expert reports or depositions. 4 Q. With regard to the condition 5 sprue-like enteropathy, what are the 6 characteristics of that syndrome? 7 A. Sprue-like enteropathy, are 8 you referring to olmesartan enteropathy 9 as sprue-like enteropathy that's been 10 variously called sprue-like enteropathy 11 associated with enteropathy, olmesartan 12 enteropathy, or olmesartan-induced 13 enteropathy? Is that what you mean? 14 Q. Correct. 15 A. There are a number of 16 characteristics. It is a clinical 17 diagnosis that takes into account a 18 number of parameters on a number of 19 different axes. There are histological 20 features. There are clinical features 21 and there are temporal features. 22 And I would say there's no 23 one case that is the platonic ideal of 24 olmesartan enteropathy, but there are</p>
<p style="text-align: right;">Page 99</p> <p>1 small bowel disease with a certain cell 2 line. 3 But I was aware that this 4 cell line has been used and so -- in the 5 study of small bowel disease, and so I 6 did a quick search and I thought that 7 that was illustrative of that point. 8 I wasn't aware at the time 9 that it was even a matter of dispute that 10 CACO cells could be used to study small 11 bowel disease. I took it for granted, 12 curse of knowledge once again. But once 13 I saw that even that was up for question, 14 I told myself, wait a minute, of course 15 there's literature on this and so I found 16 that. That is just one of the examples. 17 Q. And various of these other 18 articles you included on this 19 supplemental list because you saw them 20 referenced in one or more expert reports 21 that you had reviewed? 22 A. So, again, there was a mix 23 of reasons why these made it onto the 24 supplemental list, but one of those was,</p>	<p style="text-align: right;">Page 101</p> <p>1 various features that have been reported. 2 Q. When you say that there are 3 various, they vary from patient to 4 patient; is that correct? 5 A. The features can vary from 6 patient to patient, just like in a heart 7 attack, it's reasonable, especially 8 colloquially, to say, a heart attack, the 9 features are chest pain. But there are 10 plenty of people who have a heart attack 11 or a myocardial infarction don't have 12 that. Now, that is a clinical entity 13 that has much more of a studied track 14 record, so there have been formal 15 definitions. 16 That's not the case in 17 olmesartan enteropathy at this point 18 because it's, A, new and, B, inadequately 19 recognized and studied. 20 Q. Now, one thing I neglected 21 to ask you is whether there were any 22 deposition transcripts that you reviewed 23 after you finished or concluded your 24 report.</p>

<p style="text-align: right;">Page 102</p> <p>1 A. Yes, there were.</p> <p>2 Q. Which were they?</p> <p>3 A. I reviewed a deposition just</p> <p>4 the other day by Stephen Lagana. I</p> <p>5 reviewed a deposition recently by Dr.</p> <p>6 Daniel Leffler. And I'm not sure if</p> <p>7 there were others, but perhaps if I look</p> <p>8 at my reliance list?</p> <p>9 MR. SLATER: He's talking</p> <p>10 about subsequent to that.</p> <p>11 THE WITNESS: I'm not sure</p> <p>12 if there are others. I can't</p> <p>13 recall any at the moment, but --</p> <p>14 BY MR. MURPHY:</p> <p>15 Q. Have you read Dr. Kessler's</p> <p>16 deposition?</p> <p>17 A. I did not read Dr. Kessler's</p> <p>18 deposition.</p> <p>19 Q. But you do recall having</p> <p>20 read Dr. Leffler's deposition transcript</p> <p>21 and Dr. Lagana's deposition transcript.</p> <p>22 A. I read both of those</p> <p>23 transcripts.</p> <p>24 Q. Earlier, when I had asked</p>	<p style="text-align: right;">Page 104</p> <p>1 about to, and I think that this is</p> <p>2 particularly relevant for two reasons --</p> <p>3 Q. That's fine. I simply want</p> <p>4 to make sure that we are working off the</p> <p>5 same list so it's easy to follow where</p> <p>6 you are, and we have a couple lists out</p> <p>7 there. We have your supplemental</p> <p>8 reliance list. We also have the reliance</p> <p>9 list that initially accompanied your</p> <p>10 report. Okay?</p> <p>11 MR. SLATER: He's using the</p> <p>12 index to the literature.</p> <p>13 MR. MURPHY: That's fine. I</p> <p>14 would like him to use --</p> <p>15 MR. SLATER: You can't tell</p> <p>16 him what to reference --</p> <p>17 MR. MURPHY: No, no, no -- I</p> <p>18 beg your pardon?</p> <p>19 MR. SLATER: You can't tell</p> <p>20 him what to reference.</p> <p>21 MR. MURPHY: No. What I can</p> <p>22 do is, I can make reference to the</p> <p>23 things that he's provided in the</p> <p>24 litigation. And what he's</p>
<p style="text-align: right;">Page 103</p> <p>1 you about your opinion and you explained</p> <p>2 that there was a -- that literature taken</p> <p>3 as a whole -- body of evidence, as a</p> <p>4 whole, supported this conclusion, I</p> <p>5 wanted to ask the question, but now I</p> <p>6 think it's appropriate given the list in</p> <p>7 front of you, which articles reach the</p> <p>8 conclusion, Dr. Lebwohl, that olmesartan</p> <p>9 causes sprue-like enteropathy?</p> <p>10 A. I think that there are a</p> <p>11 number. Some of the articles are more</p> <p>12 explicit than others, but certainly the</p> <p>13 word "cause" and "induce," which I take</p> <p>14 as analogous to "cause," are out there in</p> <p>15 the literature and they're out there more</p> <p>16 and more.</p> <p>17 So, for example, in</p> <p>18 commentary by Dr. Talley --</p> <p>19 Q. If I can stop you for a</p> <p>20 second, because I'd like to follow with</p> <p>21 you --</p> <p>22 A. Is it all right if I read</p> <p>23 what Dr. Talley wrote? Because I thought</p> <p>24 that this is pretty compelling and I was</p>	<p style="text-align: right;">Page 105</p> <p>1 provided is his reliance list and</p> <p>2 the supplemental list that you</p> <p>3 were good enough to provide last</p> <p>4 night, and that's what I would</p> <p>5 like him to look to to identify</p> <p>6 those articles.</p> <p>7 MR. SLATER: Look, do you</p> <p>8 want a copy of the Table of</p> <p>9 Contents? I mean, he's -- you</p> <p>10 have all those articles. You can</p> <p>11 take your time and look to them.</p> <p>12 He's going to look at whatever he</p> <p>13 wants. It's right in front of</p> <p>14 him.</p> <p>15 MR. MURPHY: Adam, I'm</p> <p>16 simply trying to make it easier</p> <p>17 for all of us to follow along.</p> <p>18 MR. SLATER: I think it's</p> <p>19 not going to be as tough as you</p> <p>20 think it is. He's going to tell</p> <p>21 you the title and you can find it</p> <p>22 on the list and he can go to the</p> <p>23 next one.</p> <p>24 It'll be easier; it will be</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 106	Page 108
<p>1 fine. It'll be longer the way you 2 want to do it. 3 MR. MURPHY: No, it's not, 4 but we'll -- 5 MR. SLATER: It is. You can 6 go back to what you were saying. 7 MR. MURPHY: We won't fight. 8 I have your supplemental list. I 9 have your initial list. The 10 article that you were going to 11 first identify is which one, 12 Doctor? 13 THE WITNESS: It's by 14 Nicholas Talley. I believe 15 Nicholas is his first name. 16 MR. MURPHY: So give me an 17 opportunity to find Nicholas 18 Talley between these two. 19 (Pause.) 20 MR. MURPHY: Okay. 21 THE WITNESS: Are you ready? 22 Because I was going to answer the 23 question more fully. I'm not 24 finished with my answer.</p>	<p>1 that's what I'm asking about. 2 MR. SLATER: He was 3 answering the question. 4 MR. MURPHY: Okay. I -- go 5 ahead. 6 THE WITNESS: Some of these 7 articles take even for granted 8 that it causes sprue-like 9 enteropathy -- that olmesartan 10 causes sprue-like enteropathy and, 11 again, I have not encountered 12 anyone in the peer-reviewed 13 literature taking a view to the 14 contrary, saying that I do not 15 believe that olmesartan causes 16 sprue-like enteropathy in a subset 17 of individuals. 18 It is so accepted that often 19 the use of the term "cause" or 20 "induce" is not in a conclusion 21 section, but even in the 22 introduction or elsewhere. 23 Here's one. Lebwohl and 24 Ludvigsson, editorial, "Sprue-like</p>
Page 107	Page 109
<p>1 MR. MURPHY: I simply wanted 2 you to identify the article. If 3 you want to further explain, there 4 will be an opportunity for Mr. 5 Slater to explain -- or give you 6 the chance to explain why you 7 think that's the case. 8 I, at this point as I'm 9 asking the questions, I just want 10 the name of the article. 11 THE WITNESS: But there are 12 multiple articles. 13 MR. MURPHY: That's fine. 14 So let's go to the next one. 15 THE WITNESS: So the first 16 was, as I said, Talley, Annals of 17 Internal Medicine. 18 The next one mentioning 19 causation or causality -- 20 BY MR. MURPHY: 21 Q. And I just want to make sure 22 that we are on the same question. Which 23 articles that you've read conclude that 24 olmesartan causes sprue-like enteropathy,</p>	<p>1 enteropathy due to olmesartan and 2 other angiotensin receptor 3 blockers - the plot thickens." 4 You'll note that the word "due to" 5 is in the title, but the word 6 "cause" is also in table 1 of that 7 article. 8 BY MR. MURPHY: 9 Q. Okay. Do you have another? 10 A. I have others, yeah. 11 Q. Okay. 12 A. Marild and colleagues, 13 Marild, Lebwohl, Green, Murray, 14 Ludvigsson, "Blockers of angiotensin 15 other than olmesartan in patients with 16 villous atrophy: a nationwide 17 case-control study," I would note that 18 olmesartan causes enteropathy. 19 Q. M-A-R-I-L-D? 20 A. Yeah, though the A has one 21 of those small, little angstrom Swedish 22 symbols above it. I believe there are 23 others. 24 "Sprue-like histology in</p>

Page 110	Page 112
<p>1 patients with abdominal pain taking 2 olmesartan compared with other 3 angiotensin receptors blockers," Lagana, 4 Braunstein, Arguellas-Grande, Bhagat, 5 B-H-A-G-A-T, Green, and Lebwohl. 6 I believe there are others. 7 I would say in a more circumspect, but 8 more convincing manner, Rubio-Tapia in 9 the initial case series suggest causality 10 in a manner of caution. That would be 11 "Severe sprue-like enteropathy associated 12 with olmesartan." 13 Q. Well, let me -- I just want 14 to ask you a question about that: Isn't 15 it the case that Rubio-Tapia, et al 16 stated that the case series lacks all the 17 information necessary to prove causality? 18 A. This is why I gave that 19 caveat that it's more circumspect, but 20 that's not the end of the story. If we 21 look in Rubio-Tapia's article, while they 22 do mention that cautious statement -- 23 they make that cautious statement, they 24 also note the following: "Resolution of</p>	<p>1 olmesartan is a cause of sprue-like 2 enteropathy, I think I would be remiss if 3 I didn't note that, in the conclusion 4 section, they're saying think about 5 medications as a cause. 6 Q. Okay. I take your 7 explanation -- 8 A. I would say though that -- 9 and I acknowledged it when I brought this 10 up as a specific article -- it wasn't 11 quite as forceful as, for example, the 12 conclusion by Talley, which of course had 13 the benefit of numerous additional case 14 reports, a study Basson and colleagues, 15 and time. Talley is significantly more 16 forceful in terms of his opinion on 17 cause. 18 Q. So the Lagana, Marild, 19 Lebwohl, and Talley articles are in your 20 view a bit more forceful than the 21 Rubio-Tapia article with regard to 22 causation pronouncement; is that fair to 23 say? 24 A. I would say those other</p>
Page 111	Page 113
<p>1 the presenting symptoms and subsequent 2 histologic improvement after suspension 3 of olmesartan and the absence of clinical 4 evidence of other diseases associated 5 with enteropathy suggests that the 6 association is not likely to be due to 7 chance." So they are getting there. 8 And then in their 9 conclusion, they write, "Physicians who 10 encounter patients with diarrheal 11 syndromes should consider medications as 12 a cause." 13 So they're using the 14 language of causality, though I 15 acknowledge in this particular study, 16 because they really were the first to 17 characterize it, they were being quite 18 conservative and cautious in their 19 scientific terminology. 20 Q. Nonetheless, you believe 21 that what this article concludes is that 22 olmesartan causes sprue-like enteropathy. 23 A. I think that when 24 enumerating literature that conclude that</p>	<p>1 articles do not exercise as much walking 2 back as Rubio-Tapia and colleagues do, 3 which makes -- makes sense given that the 4 subsequent authors had the benefit of 5 further data and time. 6 There are others that are 7 similar to these -- 8 Q. Similar to which? 9 A. Similar not to the 10 Rubio-Tapia, but to those other articles 11 that I mentioned that mention 12 olmesartan-induced enteropathy, either in 13 the title, the abstract, or elsewhere in 14 the manuscript, not always in the 15 conclusion, but I would add that that's 16 because this is something that is taken 17 as a given in the community that studies 18 this. 19 Q. You were able to identify 20 four articles before we got to 21 Rubio-Tapia. Are there others that fit 22 into the category of the first four you 23 gave me -- 24 A. I believe there are.</p>

Protected Information - Benjamin Lebwohl, M.D., M.S.

Page 114	Page 116
<p>1 Q. -- that you want to identify</p> <p>2 for me?</p> <p>3 A. Why don't I take a look.</p> <p>4 Q. Please do.</p> <p>5 A. I think the Basson paper</p> <p>6 does address the issue of causality.</p> <p>7 Q. It reaches a conclusion</p> <p>8 regarding causality; is that what you're</p> <p>9 saying?</p> <p>10 A. Not exactly.</p> <p>11 Q. Or does it assume from the</p> <p>12 beginning that causality exists?</p> <p>13 A. Let's look at how the Basson</p> <p>14 paper ends. Basson and colleagues write,</p> <p>15 "This paper shows with a higher level of</p> <p>16 evidence the association between</p> <p>17 intestinal malabsorption and olmesartan</p> <p>18 exposure"; and then a couple of sentences</p> <p>19 later, "Patients treated with olmesartan</p> <p>20 should be informed about the risk of this</p> <p>21 complication and should be advised to</p> <p>22 seek medical attention if they experience</p> <p>23 GI symptoms."</p> <p>24 So while they do not in all</p>	<p>1 that they had available to them and they</p> <p>2 looked at codes relating to</p> <p>3 hospitalization for malabsorption --</p> <p>4 Q. Right.</p> <p>5 A. -- and also for celiac</p> <p>6 disease.</p> <p>7 Q. So my question --</p> <p>8 A. They were looking really for</p> <p>9 a surrogate for enteropathy. After all,</p> <p>10 there's no international classification</p> <p>11 of diseases code for sprue-like</p> <p>12 enteropathy induced by olmesartan. There</p> <p>13 might be in the future, but right now</p> <p>14 there isn't, and especially in the days</p> <p>15 before this was widely at least reported</p> <p>16 to be a problem with olmesartan.</p> <p>17 This is what they had and so</p> <p>18 that's what they used.</p> <p>19 Q. So with regard to the</p> <p>20 features of the sprue-like enteropathy,</p> <p>21 olmesartan-associated enteropathy, is</p> <p>22 malabsorption a common feature?</p> <p>23 A. It is a clinical feature,</p> <p>24 though --</p>
Page 115	Page 117
<p>1 capital letters say olmesartan causes</p> <p>2 enteropathy, they certainly suggest it,</p> <p>3 because why would a group of</p> <p>4 investigators say if you're taking this</p> <p>5 medicine and you have these symptoms, you</p> <p>6 need to get this checked out if they</p> <p>7 thought that this was an association and</p> <p>8 a correlation rather than causation?</p> <p>9 Because that's really what</p> <p>10 we're trying to tease apart when we have</p> <p>11 some people who use the word</p> <p>12 "association" and some people use the</p> <p>13 word "cause" or "induce."</p> <p>14 Typically, the real question</p> <p>15 is, is there a third variable lurking?</p> <p>16 And if Basson and colleagues believe that</p> <p>17 a third variable were lurking, they would</p> <p>18 not be telling patients to go check this</p> <p>19 out if you're on olmesartan.</p> <p>20 Q. I understood you to say --</p> <p>21 and I think we understand -- that Basson,</p> <p>22 et al were looking at malabsorption;</p> <p>23 correct?</p> <p>24 A. Basson, et al used the data</p>	<p>1 Q. I said common feature. Is</p> <p>2 it a feature that is common to all who</p> <p>3 have been diagnosed or are suspected of</p> <p>4 having that condition?</p> <p>5 A. Malabsorption in and of</p> <p>6 itself is not necessary for sprue-like</p> <p>7 enteropathy. Malabsorption in and of</p> <p>8 itself is actually -- has been defined in</p> <p>9 different ways by different individuals.</p> <p>10 There can be clinical</p> <p>11 malabsorption based solely on the fact</p> <p>12 that the patient reports seeing changes</p> <p>13 in one's bowel movement that looks like</p> <p>14 fat in the toilet -- and I apologize if</p> <p>15 I'm being explicit -- there is</p> <p>16 malabsorption which is declared based on</p> <p>17 the presence of deficiencies of various</p> <p>18 vitamins, and then there's malabsorption</p> <p>19 that's based on formal stool testing and</p> <p>20 other testing.</p> <p>21 Malabsorption therefore is a</p> <p>22 somewhat broad term that's defined</p> <p>23 variously in the medical literature and</p> <p>24 in clinical practice. And so to say that</p>